Remarks:

In view of the follow remarks, reconsideration of this application, and withdrawal of the rejections and formal notification of the allowability of all claims are respectfully requested.

Status of Claims

Claims 1-10, 12, 15, 17-19, 21-25, 27, 29, 31-45, 48, 62-70, 74, 76-85 are pending.

Claims 1, 6, 19, 21, 24, 29, 31, 34, 45, 62, 69, and 70 have been amended to overcome the pending rejections under 35 U.S.C. §§112, 102 and 103.

Claims 13, 14, 28, 46, 47, 49-61, 71-73 and 75 have been withdrawn form further consideration in response to the Examiner's restrictions/election requirement.

Claims 11, 16, 20, 26 and 30 have been cancelled.

Written Support for Amended Claims

Written support for each of the amended claims can be found in the specification in at least the following sections as provided in Published Application US2005/007/4405A, published 4/7/06: ¶¶'s 35, 28, line 6, original claim 9-10, ¶28, ¶40, line 4; ¶45, line 2; and ¶35.

Claim Rejections – 35 USC §112

Claims 8 and 23 have been rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. According to the Examiner:

> [Claims 8 and 23] contain subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification, as originally filed, shows certain specific amounts of barium, such as 0.01%, 0.02%, 0.03%, etc., it does not show support for the full range of concentrations from about 0.01 to about 0.2% w/v.

Office Action, pp. 3-4.

In response to the Examiner's rejection, applicants point out that written support for the range "about 0.01 to about 0.2% w/v" can be found, for example, in original Claims 10, 44 and 85, as filed. See originally filed application.

Also, Claims 34-44 have been rejected under 35 U.S.C. § 112, second paragraph. According to the Examiner, these claims are ambiguous because it is allegedly unclear what diagnostic procedure is covered by the claims. In response to the Examiner's rejection, independent 34 has been amended to recite "a method for imaging an anatomic segment, tissue or organ inside an individual's body". Applicants believe that the amendment to Claim 34 overcomes the Examiner's indefinite rejection. Claims 35-44 depend from amended Claim 34, and therefore overcome the Examiner's rejection for the reasons specified above.

Claim Rejections – 35 USC §102(b)

The Falasch Reference (DD 23830).

Claims 1-7, 12, 15 and 17 were rejected as being anticipated by Falasch. According to the Examiner, Falasch teaches a contrast media comprising 1% w/v barium sulfate having a measured Hounsfield Value ("HV") of less than 200. According to the Examiner, Falasch discloses a barium-sulfate suspension for x-ray diagnostics. Here, according to the Examiner, barium sulfate represents 0.5% to 2.0% of the compositions.

As amended, Falasch does not anticipate Claim 1, which now recites the inclusion of a sugar alcohol. The specification makes clear that an osmotic agent (e.g. sugar alcohol) controls the absorption and re-absorption of fluid in an anatomic segment to facilitate luminal distension. The Falasch formulation does not include a sugar alcohol. Accordingly, Falasch does not meet each limitation of amended claim 1, and therefore cannot anticipate that claim. Also, since claims 12, 15 and 17 dependend from claim 1, they too cannot be anticipated by Falasch for the same reasons specified above.

The Tait Reference (US2001/0036882)

The Examiner has also rejected Claims 1-7, 12, 15, 17, 18, 34-41, 45, 46, 48, 62-64, 70, 74 and 76-82 as anticipated by Tait. According to the Examiner, the Tait formulation comprises barium sulfate in an amount ranging from 0.5% to 1.5% w/v per volume, and that it also comprises xanthan gum.

The Tait reference does not anticipate independent claims 1, 34, 45, 62, 69 and 70, as currently amended. Each of these claims require the inclusion of a sugar alcohol. The Tait formulation has no sugar alcohol, because such formulation facilitates the incorporation of barium into stool. It is not directed to distending an anatomical segment for purposes of improving image quality. Therefore, an osmotic agent (e.g., carbohydrate alcohol) is of no value in the Tait formulation. Accordingly, Tait does not meet each limitation of amended claims 1, 34, 45, 62, and 70, and therefore cannot anticipate those claims. Also, claims 2-7, 15, 17, 18, 33-41,46,48, 62-64, 70, 74 and 76-82 depend from either independent claims 1, 34, 45, 62, 69 and 70, and therefore the dependent claims cannot not be anticipated by Tait for the same reasons the afore-mentioned independent claims are not anticipated by that reference.

The Litt Reference (Litt et al., A Cad. Radiol, 2001)

The Examiner further rejects Claims 1-8, 10 and 12 as anticipated by the Litt reference. According to the Examiner, Litt discloses agarose containing barium sulfate for constructing multimodality imaging phantoms. The Examiner notes that the Litt composition contains 0.25% - 6% wt/vol. barium suspension.

The Litt reference does not anticipate claims 1-8, 10 and 12. Each of these claims, as amended, requires the inclusion of a sugar alcohol. The Litt formulation does not include such an agent. Accordingly, claims 1-8, 10 and 12 are not anticipated by Litt.

The Raptopoulos Reference (Radiology, 1987, 164, p.653-56)

The Examiner further rejects claims 62-64, 66, 68-70, 74 and 76-80 as anticipated by the Raptopoulos reference. According to the Examiner, the Raptopoulos reference discloses the use of a 12.5% corn oil emulsion for abdominal CT in humans. The Examiner indicates that Raptopoulos reports adequate gastric distention, and that the entire stomach and duodenum were distended throughout examination.

The Raptopoulos reference does not anticipate claims 62-64, 66, 68-70, 74 and 76-80, as amended. Each of these claims require as limitations the inclusion of: (i) barium sulfate; and (ii) a sugar based osmotic agent, namely a sugar alcohol. Neither of these claim elements are present in the Raptopoulos formulation. Therefore, Raptopoulos cannot anticipate the subject claims.

The Lefere Reference (US2905/0175542)

The Examiner further rejected claims 1-10, 12, 15, 16, 19-22, 34-26, 29-45, 48, 62, 64 and 69-85 as anticipated by the Lefere reference. The Lefere reference has a common inventor and common assignee with the instant application. Submitted herewith is the 37 CFR 1.32 Declaration of Archie Williams inventor of the claimed inventions of the present application. In the Declaration at ¶¶26-27, Mr. Williams declares that he conceived of the relevant portion of the subject matter disclosed in the Lefere reference and relied on by the Examiner prior to April 2, 2002, which is the earliest filing date of the Lefere reference. The Lefere reference is, therefore, not prior art to the instant application.

Claim Rejections 35 U.S.C. §103(a)

Claims 1-10, 12-45, 48, 62, 64 and 69-85

The Examiner has rejected claims 1-10, 12-45, 48, 62, 64 and 69-85 as being obvious over Tait in view of Lefere. The Lefere reference has a common inventor and common assignee with the instant application. Submitted herewith is the 37 CFR 1.32 Declaration of Archie Williams inventor of the claimed inventions of the present application. In the Declaration at ¶¶26-27, Mr. Williams declares that he conceived of the relevant portion of the subject matter disclosed in the Lefere reference and relied on by the examiner prior to April 2, 2002, which is the earliest filing date of the Lefere reference. The Lefere reference is, therefore, not prior art to the instant application.

Claims 1-7, 12, 15-27, 29-41, 45, 48, 62, 69, 70, 74 and 76-82

The Examiner has rejected claims 1-7, 12, 15-27, 29-41, 45, 48, 62, 69, 70, 74 and 76-82 as obvious over Falasch in view Nyman and Fuisz. Applicant respectfully disagrees with the Examiner's rejections.

Specifically, the Examiner contends that Falasch discloses barium sulfate suspensions stabilized with clay in aqueous solutions. The Examiner also contends that Nyman and Fuisz overcome the short falls of Falasch. According to the Examiner, Nyman teaches barium sulfate (1.7% w/v) mixed with sorbitol (osmotic agent) and vegetable gum (stabilizing agent). The Examiner points out that Nyman does not specify the amounts of these ingredients in the formulations disclosed therein. However, according to the Examiner, Fuisz does teach the same amounts of sugars and vegetable gums, in combination with barium sulfate, as those recited in the pending claims.

As previously mentioned, applicant has amended all independent claims (claims 1, 34, 45, 62 and 70) to require a sugar alcohol. The rejected claims also require a low concentration of barium sulfate (about 0.01% w/v to about 0.5% w/v). Here, the attenuation of a low-concentration of barium sulfate is less than 50 HU. Applicant has found that this attenuation level, in combination with a sugar alcohol in an aqueous medium, provides improved evaluation of the large intestine and small bowel, among others things. Moreover, the low concentration of barium, in combination with a sugar alcohol, distends the lumen far better than other known contrast agents. *See* Declaration of Archie Williams, which is attached hereto.

The Falasch formulation contains no sugar alcohol. Given the claims as amended, applicant submits that Falasch can no longer stand as an appropriate primary reference. Further, nothing in Nyman suggests that significantly decreasing the concentration of barium sulfate by almost 70% (1.7% v. 0.5%), in combination with sugar alcohol, would greatly improve luminal distention and imaging properties of a contract medium. *See* Declaration of Archie Williams, ¶ 9.

Moreover, the Examiner's reliance on Fuisz is misplaced. Unlike the claimed invention, Fuisz is not directed to a formulation comprising: (i) barium sulfate; (ii) an osmotic agent; and (iii) gum dissolved and/or suspended in an aqueous medium. Instead, it is directed to melt-spinning sugar (maltodextrin) and gum onto barium sulfate particles to produce a matrix in the form of barium flakes. See e.g., Fuisz col. 2, lines 45-49;

col. 3, lines 37-40; col. 4, lines 36-44, and 52-61. Here, the barium sulfate, maltodextrin and gum are not used as separate ingredients to form an aqueous suspension. Therefore, whatever amounts of maltodextrin and gum disclosed in Fuisz, in combination with barium sulfate, are not applicable to the present invention. To further distinguish over Fuisz, the present claims have been amended to make clear that the claimed invention is directed to an aqueous suspension comprising a low concentration of barium sulfate and a carbohydrate alcohol sugar, as distinguished from a gum/maltodextrim base matrix mixed with water, which is disclosed in Fuisz. *See* Fuisz, col. 15, lines 5367. In short, there is nothing in Fuisz that would have motivated a person of ordinary skill to combine the prior art (Falasch and Nyman) in the manner recited in the claims. In fact, the relevance of Fuisz to the present invention is tenuous at best, and one skilled in the art would not look to Fuisz for guidance in developing an aqueous suspension of barium sulfate of the kind claimed in the patent application.

The Claimed Invention Possesses Unexpected Improved Properties The Prior Art Lacks

A patent applicant may successfully rebut an obviousness rejection by demonstrating "unexpected results," i.e., to show that the claimed invention exhibits some improved property or advantage that a person of ordinary skill in the art would have found surprising or unexpected. The basic principle behind this rule is straightforward --- "that which would have been surprising to a person skilled in the art would not have been obvious." *In re Soni*, 54 F.3d 746 (Fed. Cir. 1995). Further, unexpected results in support of patentabilty must be established by evidence and not simply argument or conclusory statements in the specification. A claimed invention must show superior results compared with the results achieved with the closest prior art. *In re Blauwe*, 736 F.2d 699 (Fed. Cir. 1984).

As mentioned, the Falash composition contains no sugar alcohol. Also, Fuisz does not disclose an aqueous suspension comprising a low concentration of barium sulfate in combination with a sugar alcohol. Therefore, the closest prior art in terms of barium concentration and the amount of sugar alcohol in an aqueous suspension consists of two commercially available contrast agents, E-Z-CAT® and ReadiCat®. *See* Williams Declaration, ¶ 9. Nyman discloses the use of E-Z-CAT®. The claimed invention possesses unexpected improved imaging and luminal distention properties over these products, as discussed below.

E-Z-CAT® (1.7% w/v BaSO4) and Readi-Cat® (1.3% w/v BaSO4) differ in barium concentration by 0.4% w/v. *Id.*, ¶ 10. As contrast agents, both products possess similar drawbacks with respect to luminal distention and imaging of the digestive tract, including but not limited to the stomach, large intestine and the bowel wall. *Id.* For example, both E-Z-CAT® and Readi-Cat® exhibit about the same level of brightness on a CT Scan. *Id.* This is because their respective barium sulfate concentrations exceed at least 1.0% w/v. *Id.* It has been reported that contrasts agents having at least 1.0% w/v barium sulfate can obscure certain regions of the bowel during an imaging procedure. *Id.* This set back is illustrated by the CT images below (Figures A and B). *Id.*

Specifically, these images show the difference between an oral contrast agent having >1.0% w/v barium sulfate (Readi-Cat®) (Figure A) and an agent of the claimed invention, i.e., an agent having ≤0.5% w/v barium sulfate (e.g., VoLumen® - 0.1% w/v barium sulfate) (Figure B) in the same patient. *Id.* In this study, a 54-year-old female with Chrohn's disease and fistula was subject to two separate multi-detector computer tomography ("MDCT") examinations. *Id.* In each examination, the patient was administered 900 ml to 1,000 ml of either Readi-Cat® or VoLumen® over a 45-minute period. *Id.* Immediately prior to scanning the patient, an additional 7 ounces (207 ml) was administered to distend the stomach. *Id.* Figures A and B represent images taken from the two separate examinations. *Id.*

In Figure A, the bright white oral contrast is obscuring the surrounding soft tissue and enhancement of the bowel wall. *Id.*, ¶12. In the VoLumen® image (Figure B), which reflects the claimed invention, enhancement of the mucosal surface is observed. *Id.* This image shows inflammation/active disease in the internal bowel wall lining (mucosa) and edema in the thickened walls, as well as lesions in the lumen, which are obscured by the oral contrast with barium concentrations exceeding 1.0% w/v (Figure A). *Id.*

Figure A.

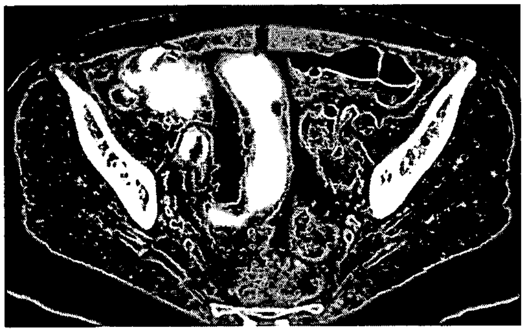
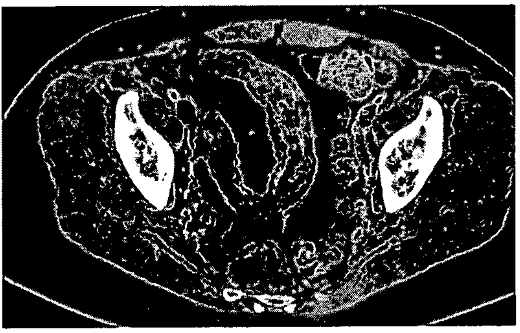


Figure B.



The above CT images demonstrate the unexpected improved imaging and luminal distention properties of the claimed invention, namely a contrast agent having a carbohydrate alcohol in combination with a low concentration of barium sulfate(≤ 0.5% w/v), over the prior art such as Readi-Cat®, as well as E-Z-CAT®, which is disclosed in Nyman. *Id.*, ¶ 13_.

The publication attached as Exhibit 1 to the Williams Declaration further demonstrates that the claimed composition possesses an unexpected high degree of luminal distention and imaging, which is not suggested by the cited prior art. *Id.*, ¶ 14. This publication is entitled "Evaluation of Bowel Distention and Bowel Wall Appearance by Using Neutral Oral Contrast Agent for Multi-Detector Row CT", *Radiology*:

Volume 238: Number 1- January 2006 (hereafter the "Megibow study")[1]. *Id.* In this study, the performance of the claimed invention (e.g., VoLumen®) as a bowel-marker agent is compared to the prior art barium suspension, Readi-Cat®. *Id.* As mentioned, the barium concentration of VoLumen® and Readi-Cat® is 0.1% w/v and 1.3% w/v, respectively. *Id.* Also, VoLumen® contains additives similar to those in Readi-Cat®. *Id.*

The Megibow Study shows that the maximal distension in the stomach, duodenum, jejunum, ileum and small bowel after administration of VoLumen® was significantly higher than that obtained after the administration of Readi-Cat®. See *Id.*, ¶ 15. For example, Table 4 shows the results of a quantitative analysis of patients receiving VoLumen®; Readi-Cat®; and water/methylcellulose. *Id.* These results show that the maximal distention in the duodenum after administration of VoLumen® was significantly higher than that obtained after administration of either Readi-Cat® or water/methylcellulose. *Id.* Also Figure 1 of the Megibow study shows that VoLumen® successfully produced significant visual enhancement within the stomach, duodenum, and small bowel. It also facilitated the detection of disease. *Id.*

In sum, the results of the Megibow study show excellent distention and visualization properties of the claimed invention. *Id.*, ¶16. By combining a low concentration of barium sulfate with a sugar alcohol in an aqueous suspension, as currently claimed, the difference between the contrast in the bowel and the enhanced soft tissue (i.e., bowel wall) is greatly improved. *See Id.* Consequently, the image quality is much improved, such that the true boundary between contrast and soft tissue can be readily discerned. *Id.* This allows for accurate visualization of the bowel wall, for example, with sufficient contrast enhancement to reveal vascular supply of blood to mucosa, sub mucosa and all layers of the bowel wall, stomach, small bowel and colon, which is not necessarily achievable with E-Z-CAT®, Readi-Cat® or other commercially available contrasts agents. *Id.*

The Megibow study demonstrates that the claimed invention, namely a low concentration of barium sulfate about 0.1% w/v to about 0.5% w/v) combined with a sugar alcohol in an aqueous suspension possesses an unexpected degree of luminal distension and visualization compared with E-Z-Cat® and Readi-Cat®. See *Id.*, ¶ 17. These unexpected improved results would not have been obvious in view of the cited art. Indeed, neither Falasch, Fuisz nor Nyman suggest that significantly reducing the barium concentration, in combination with a sugar alcohol, would provide an oral contrast agent having such improved properties, as those shown in the Megibow study. *Id.*

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[1] The Megibow study was sponsored by E-Z-EM. The sponsor provided the VoLumen. The sponsor also created all data forms and instructed the physicians and their respective assistants on the randomization process. The sponsor also made random visits to the site to provide quality control monitoring and oversight. The sponsor assumed the costs of the CT scans at the institutional research rate. The authors who were employees of E-Z-EM (Carmela Houston, Micheal Boruch and Archie Williams) were blinded to all data generated during the trial. See Exhibit 1, p.88, Materials and Methods. See Williams Dec., ¶ 14.

Additionally, other commercially available neutral contrast agents (water, PEG and methyl cellulose) have been shown to be inferior to the claimed invention. See *Id.*, ¶¶ 18-20.

The Claimed Invention Satisfies a Long Felt Need

The claimed invention satisfies a long felt need for a contrast agent suitable for PET-CT and MRI scanning. See *Id.*, ¶¶ 21-25. Also the claimed invention (e.g., VoLumen®) has been used successfully in the pediatric population to evaluate the small bowel for disease. See *Id.* Further, VoLumen® is the only commercially available oral contrast agent that can be used in conjunction with Capsule Endoscopy, thus satisfying another long felt need in the art. See *Id.*

Based on the foregoing, claims 1-7, 12, 15-27, 29-41, 45, 48, 62, 69, 70, 74 and 76-82 are not obvious over Falasch in view of Nyman and Fuisz, and therefore applicants respectfully request that the Examiner's rejection be withdrawn.

Claims 1-7, 12, 15, 17, 34-41, 45, 48, 62, 63, 65, 67, 69, 70, 74, 76-82

The Examiner has also rejected claims 1-7, 12, 15, 17, 34-41, 45, 48, 62, 63, 65, 67, 69, 70, 74, 76-82 as being obvious over Falasch in view of Gore. Specifically, the Examiner contends that Falasch discloses barium sulfate suspensions in aqueous solutions. The Examiner also contends that, while Falasch does not recite a specific anatomical segment or disease which may be diagnosed, Gore teaches the use of E-Z-CAT® as a contrast agent for identifying patients with Crohn's disease and ulcerative colitis ("UC"). According to the Examiner, it would have been obvious to one skilled in the art to use the Falasch composition (0.5%-2.0% w/v barium sulfate) for imaging the colon and differentiating between patients with Crohn's disease and "UC" because Falasch teaches that its barium formulation is suitable for x-ray imaging. Also, according to the Examiner, one would have been motivated to use the Falasch formulation because Gore teaches that a similar barium formulation (E-Z-CAT®) is capable of achieving such actions. Applicant respectfully disagrees with the Examiner's rejections.

As previously mentioned, applicant has amended all independent claims (claims 1, 34, 45, 62 and 70) to require a sugar alcohol. The rejected claims also require low concentration of barium (about 0.1% w/v to about 0.5% w/v). The attenuation of low-concentration barium is less than about 50 HU. Applicant has discovered that this attenuation level, in combination with a sugar alcohol in an aqueous suspension, provides improved evaluation of the large intestine and small bowel, among other anatomical sections of an individual's digestive tract and other organs. Moreover, the low concentration of barium, in combination with an alcohol sugar, distends the lumen far better than other known contrast agents. *See* Williams Dec., ¶ 9.

The Falasch formulation contains no alcohol sugar. Given the claims as amended, applicant submits that Falasch can no longer stand as an appropriate primary reference. Further, nothing in Gore suggests that significantly decreasing the concentration of barium by almost 70% (1.7% v. 0.5%), in combination with an alcohol sugar, would greatly improve luminal distention and imaging of an individual's anatomic segment. *See* Williams Dec., ¶ 9.

Further, as shown in the Williams Declaration, the claimed invention has unexpected improved imaging and luminal distention properties over the closet prior art such as Readi-Cat®, as well as E-2-CAT®, which is disclosed in Gore. See Williams Declaration. Moreover, the claimed invention satisfies a long felt need for a contrast agent suitable for PET-CT, MRI scanning, and Capsule Endoscopy. See *Id.*

Based on the foregoing, claims 1-7, 12, 15, 17, 34-41, 45, 48, 62, 63, 65, 67, 69, 70, 74 and 76-82 are not obvious over Falasch in view of Gore.

Claims 1-10, 12, 15-27, 29-45, 48, 62, 69, 70, 74, 76-85

The Examiner has also rejected claims 1-10, 12, 15-27, 29-45, 48, 62, 69, 70, 74, 76-85 as obvious over Falasch in view of Nyman, Fuisz and Litt. According to the Examiner, one skilled in the art would have been motivated to make a contrast agent having 0.5% w/v barium sulfate, stabilizing agents and osmotic agents (xanthan gum and sorbitol) within the claimed concentration ranges, given that Falasch teaches contrast agents having the claimed barium sulfate concentration, and given that Nyman teaches combining barium sulfate with gum and sorbitol. The Examiner also contends that, while Nyman does not teach the specific claimed concentrations of gum and sorbitol, it would have been obvious to use concentrations such as 3% to 50% xanthan gum and from 10% to 20% sorbitol in view of Fuisz. The Examiner further contends that it would have obvious to use a low concentration of barium sulfate, such as 0.25% in view of Litt. Applicant respectfully disagrees with the Examiner's rejections.

As previously mentioned, applicant has amended all independent claims (claims 1, 34, 45, 62 and 70) to require a sugar alcohol. The rejected claims also require a low concentration of barium sulfate (i.e. about 0.01% w/v to about 0.5% w/v). The attenuation of low-concentration barium is less than about 50 HU. Applicant discovered that this attenuation level, in combination with a sugar alcohol in an aqueous suspension, provides improved evaluation of the large intestine and small bowel, among anatomical sections of an individual's digestive tract and other organs. Moreover, the low concentration of barium, in combination with a sugar alcohol, distends the lumen far better than other known contrast agents. *See* Williams Dec.

The Falasch formulation contains no alcohol sugar. Given the claims as amended, applicant submits that Falasch can no longer stand as an appropriate primary reference. Further, nothing in Nyman suggests that significantly decreasing the concentration of barium by almost 70% (1.7% v. 0.5%), in combination with sugar alcohol, would greatly improve luminal distention and imaging of an individual's anatomic segment. *See* Id.

Moreover, the Examiner's reliance on Fuisz is misplaced. Fuisz is not directed to a formulation comprising: (i) barium sulfate; (ii) an osmotic agent; and (iii) gum dissolved and/or suspended in an aqueous suspension. Instead, it is directed to melt-spinning a sugar (maltodextrin) and gum onto barium sulfate particles to produce a matrix in the form of barium flakes. *See* e.g., Fuisz col. 2, lines 45-49; col. 3, lines 37-40; col. 4, lines 36-44, and 52-61. Here, the barium sulfate, maltodextrin and gum are not used as separate ingredients to form an aqueous suspension. Therefore, whatever amounts of maltodextrin and gum disclosed in Fuisz, in combination with barium sulfate, are not applicable to the present invention. In short, there is nothing in Fuisz that would have prompted a person of ordinary skill to combine the cited prior art in the manner recited in the claims. In fact, the relevance of Fuisz to the present invention is tenuous at best. Nonetheless, to further distinguish over Fuisz, the present claims have been amended to make clear that the claimed invention is directed to an aqueous suspension comprising a low concentration barium sulfate and a sugar alcohol as distinguished from a gum/maltodextrin/ BaSo4 matrix mixed with water, which is disclosed in Fuisz. *See* e.g., Fuisz, Col. 15, lines 53-67.

Litt is less relevant than Fuisz. Litt discloses the use of agarose containing barium sulfate to produce imaging phantoms. It does not disclose a barium based formulation suitable for administration into a patient, much less an aqueous suspension comprising barium sulfate and a sugar alcohol. One skilled in the art would not look to Litt for guidance in determining an appropriate amount of barium sulfate for use as a contrast agent in humans. Also, there is nothing in Litt suggesting that a low concentration of barium, combined with a carbohydrate alcohol, would significantly improve luminal distention and imaging of an anatomical segment when administered into a human. Simply stated, the agarose-based composition of Litt is not relevant to the claimed barium formulation, which is an aqueous suspension for administration into humans.

Based on the foregoing, claims 1-10, 15-27, 29-45, 48, 62, 69, 70, 74, 76-85 are not obvious over Falasch in view of Nyman, Fuisz and Litt.

Claims 1-10, 12, 15, 17, 34-41, 45, 48, 62, 63, 65, 67, 69, 70, 74 and 76-85

The Examiner has rejected claims 1-10, 12, 15, 17, 34-41, 45, 48, 62, 63, 65, 67, 69, 70, 74 and 76-85 as obvious over Falasch in view Gore and Litt. In response to the Examiner's rejection, applicants rely upon the arguments made herein as it concerns Falasch, Gore and Litt. *See Infra*, pp. 13-19, respectively. For these reasons, applicants respectfully submit that claims above rejected are not obvious over Falasch in view of Gore and Litt, and therefore applicants respectfully request that the Examiner's rejection be withdrawn.

Conclusion

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that fees for the net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that, and any fee is required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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Yolanda Sanchez